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Original Article

The effect of acupuncture on Bell's palsy: an overall and cumulative meta-analysis of randomized controlled trials

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Abstract: Background: Whether acupuncture is effective for Bell's palsy is controversial, and potential modifiers exist according to previous studies. Objectives: An overall and cumulative meta-analysis was conducted to evaluate and quantify this efficacy. Study appraisal and synthesis methods: Searches of PubMed, EMBASE, Wanfang database and the Cochrane Central Register of Controlled Trials were performed up to July 2016, and a random-effect model was used to yield summary relative risks (RRs). Results: Compared to conventional treatments, RRs for total effective rate and cured rate of acupuncture are 1.11 (95% confidence interval (CI)=1.05-1.17) and 1.56 (95% CI=1.30-1.87), respectively. Cumulative meta-analysis revealed that the efficacy of Bell's palsy have a stable and preferable variation tendency over time. Subgroup and sensitivity analyses suggested comparisons, acupuncture regimens and disease stages are potential confounding factors. Conclusion: In conclusion, we failed to draw a conclusion that the acupuncture is effective for facial paralysis since these limited methodological quality studies and potential biases, there need to be validated by more well designed and large sample size RCTs.

Keywords: Acupuncture, Bell's palsy, total effective rate, total cured rate, meta-analysis

Introduction

Bell's palsy, also known as acute idiopathic facial palsy, is an acute peripheral facial neuropathy which is the most common cause of lower motor neuron facial palsy [1]. Its characterized clinical symptoms include a rapid onset, unilateral, lower motor neuron-type facial weakness accompanying post auricular pain, dysgeusia, subjective change in facial sensation and hyperacusis [2]. Although Bell's palsy is uncommon, it affects people across children to adults [3], with incidence up to 53.3 per 100,000 person years in different population [4-6].

For etiology of Bell's palsy, several plausible mechanisms have been proposed, such as herpes simplex type-1 [7], nerve compression [8], autoimmunity [9]. Relevant therapies containing antiviral medicine [10], corticosteroids [11], surgery [8] and acupuncture treatment [12] are commonly applied to Bell's palsy patients. The acupuncture is a practical and cost-effective intervention with few adverse side effects which is useful for many disorders. The efficacy of acupuncture treatment on Bell's palsy have been examined for many times by meta-analyses [12-14] from Cochrane database, in spite of that, no conclusion was drawn due to restricted quality of included studies. Recently, a meta-analysis was conducted on this topic [15], which cautiously supported acupuncture curative effect. However, the high heterogeneity was found among included studies, raising concerns about the reliability of its summary results. In addition, sample size, baseline data, and intervention measures, as well as the variable evaluation criterion across different trials, may be responsible for the unstable results.

Acupuncture is among the oldest healing practices in the world. In the United States, it has been considered as one of the major therapies in complementary and alternative medicine (CAM) [16]. With arousing considerable atten-

tion to the acupuncture treatment for Bell's palsy, investigating its efficacy and potential modifiers is critical for a better understanding of this traditional Chinese medicine therapy method. Therefore, we conduct an update meta-analysis of randomized controlled trials (RCTs) to comprehensively investigate whether Bell's palsy patients would benefit from acupuncture treatment, and to further investigate confounding factors.

Materials and methods

Search strategy

This meta-analysis was performed in adherence to PRISMA statement [17]. Systematic literature searches of PubMed, EMBASE, Wanfang database and the Cochrane Central Register of Controlled Trials were conducted up to July 2016. The search strategy is showed in the Supplementary List 1 in detail. We checked the reference lists of included studies and previous meta-analysis [15, 18] for additionally eligible studies. No attempt was made to identify unpublished reports. If necessary, the original authors were contacted to obtain extra information via e-mails.

Study selection

Two investigators (Fu-ming Wang and Sha-sha Yu) independently selected the suitable publications according to following inclusion criteria: (1) Participants: subjects diagnosed with Bell's palsy. (2) Intervention: manual acupuncture or electric acupuncture. (3) Control: other therapy regimens except acupuncture. (4) Outcome: Adjusted risk estimates with 95% confidence interval (CI) on the association of acupuncture and efficacy of Bell's palsy included cured rate and effective rate. (5) Study design: RCTs. The criteria were determined with reference to the House-Brackmann judging and grading system of facial nerve function. There are 4 levels, respectively, cured, markedly effective, effective, and ineffective. The percentage of cured was called cure rate, and the percentage of markedly effective or effective were called total effective rate.

Data extraction and risk of bias assessment

Data extraction was conducted by one investigator (Fu-ming Wang), the n independently checked by another investigator (Sha-sha Yu) for the accuracy. The following information was extracted: first author, publication year, study location, sample size, mean age, disease stage.

Two investigators (Fu-ming Wang and Sha-sha Yu) independently assessed the quality of included studies using the Cochrane Handbook for Systematic Reviews of Interventions [19]. Seven aspects were evaluated as following: 1) Selection bias: random sequence generation, allocation concealment; 2) Performance bias: Using blind method to researchers and subjects; 3) Detection bias: The evaluation results of the study by the method for the blind; 4) Attrition bias: The data results integrity; 5) Reporting bias: Report the results of the study selectively; 6) Other bias: In addition to the above bias, the information provided can whether evaluate other causes of bias or not. If problems or factors are first mentioned in the protocol, those should give the corresponding answers. The "high", "moderate", "low" was allocated for each item. Any controversies on the results of data extraction and quality assessment were resolved by further discussion.

Data synthesis and analyses

In this meta-analysis, relative risk (RR) with 95% confidence intervals (CI) was considered as common measure of the association between acupuncture therapy and total effective rate or total cured rate. A random-effect model [20] was used to pool RRs to obtain the overall effect size. The between-study heterogeneity was assessed by Q statistic ($P_{Heterogeneity}$<0.10 suggesting statistically significant) and the I^2 [21] (high heterogeneity, $I^2 \geq 75\%$; moderate heterogeneity, $50.0\% < I^2 < 75\%$; low heterogeneity, $I^2 < 50\%$ [22]).

To identify potential modifiers, the study-level subgroup analysis was performed stratified by age, contrast design, acupuncture design, sample size, therapy period, disease stage, respectively, and a $P_{interaction}$ between subgroups was calculated by meta-regression [23]. To further analysis the heterogeneity between eligible studies and check the stability of pooled results, three sensitivity analyses were conducted as following: omitting a single study in turn; repeating analyses by the fixed-effects model; and employing various eligibility criteria.

Additionally, cumulative meta-analysis was conducted to evaluate the efficacy of acupuncture therapy. Eligible studies were added 1 at a

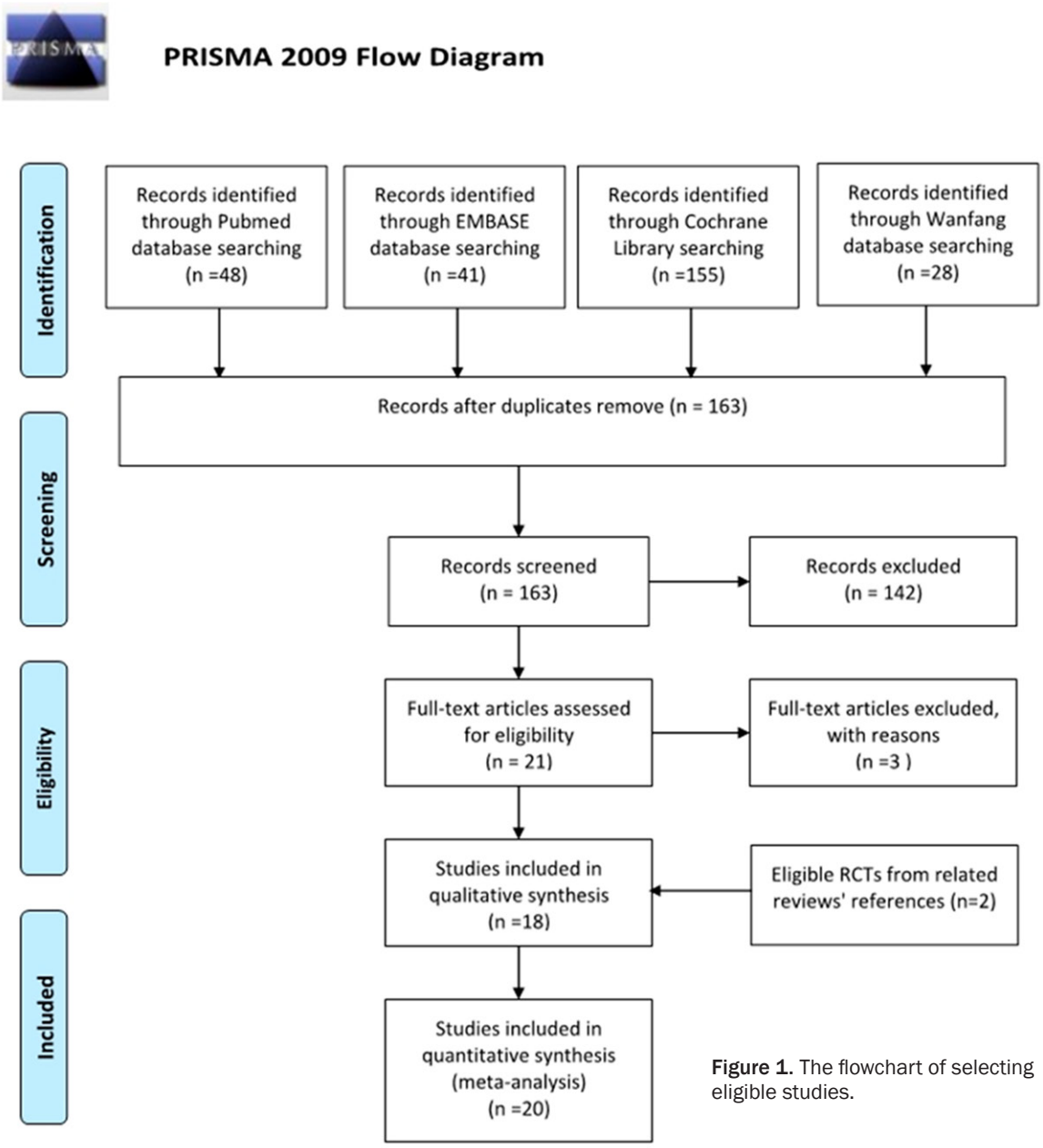

Figure 1. The flowchart of selecting eligible studies.

time in order of year of publication, and the results were summarized sequentially.

Potential publication bias was assessed by Begg rank correlation test [24] and Egger linear regression test [25]. All analyses were conducted using STATA version12.0 (StataCorp, College Station, TX) and RevMan 5.3 (The Nordic Cochrane Centre, Copenhagen, Denmark). $P<0.05$ was considered statistically significant. All statistical tests were two-sided.

Results

Study selection and characteristics

A flowchart of search selection and results is shown in **Figure 1**. We identified 244 potential-

Table 1. Characteristics of 20 eligible RCTs

Study	Sample Size	Bell's Palsy ascertainment	Efficacy assessment	Acupuncture type	Comparison	Outcome Assessment
Liu et al. 1996 China	130	Clinical diagnosis: Symptom, Sign, EMG	Clinical diagnosis: Symptoms, Signs, Electromyography	Multi-needle shallow puncture	Acupuncture: needles inserted with manual stimulation till elicited de qi; 30 min×10 treatment sessions; vs. Drug group: prednisone 20 mg three times/day, vitamin B+, dibazol	Total effective rate; The cured rate
Yu et al. 1999 China	50	Clinical diagnosis: Symptom, Sign	NR	Multi-needle shallow puncture	Acupuncture group: conventional acupuncture 20 min/day×10 sessions; vs. Drug group: vitamin B, steroid, traditional Chinese medicine	Total effective rate
Shao et al. 1999 Chian	108	NR	NR	NR	Combined group: conventional acupuncture once/day×15 d/session, rested for 4 days, another cycle; vs. Drug group: dexamethasone + vitamin B1 + vitamin B12 + citicoline + ribavirin	Total effective rate
Yang et al. 2001 China	60	NR	NR	Electroacupuncture Manual stimulation	Electroacupuncture group: needles inserted with manual stimulation till elicited de qi, electroacupuncture for 30 min/d×10 treatment sessions; vs. Observed group: therapeutic apparatus was applied for 2 min/d×10 sessions	Total effective rate
Zhu et al. 2004 China	57	NR	Facial paralysis scale	Electroacupuncture	Electroacupuncture + routing group: electroacupuncture 30 min/d×13 sessions for a cycle, rested for 2 days, another cycle, and routing group; vs. Routing group: acyclovir, traditional Chinese medicine, physical therapy	Total effective rate; The cured rate
Ma et al. 2004 China	195	Clinical diagnosis: Symptom, Sign	Clinical diagnosis: Symptoms, Signs, facial muscle function	Manual acupuncture	Acupuncture group: needles inserted with manual stimulation till elicited de qi; 30 min/d×5 treatment sessions/week, rested for 2 days, total 6 weeks; vs. Drug group: vitamin B1 100 mg/d×5 times/week, vitamin B12 250 ug/d×5 times/week, rested for 2 days, total 6 weeks	Total effective rate
Li et al. 2005 China	94	NR	NR	Electroacupuncture	Electroacupuncture group: 20 min/d×5 days/week, rested for 2 days, a total of 4 weeks; vs. Control group: Chinese traditional manipulation	Total effective rate
Zhao et al. 2005 China	42	The Facial Movement Score	The Facial Movement Score	Electroacupuncture	Electroacupuncture group: electroacupuncture 20-30 min/other day×10 sessions for a cycle; vs. Stellate ganglion block group: 10 g/L lidocaine 6-8 mL, injected at the basal of sixth cervicalvertebra transverse process	Total effective rate; The cured rate
Liang et al. 2006 China	480	House-Brackmann grading scale	The House-Brackmann grading scale The FDI scale	Manual acupuncture	Acu-moxibustion group: filiform needle plus moxibustion; vs. Basic treatment group: prednisone, vitamin B1, vitamin B12 and dibazol	The cured rate The markedly relived rate The improved rate
Zhu et al. 2006 China	108	Clinical diagnosis: Symptom, Sign	The Facial paralysis scale	Manual acupuncture	Acupuncture group: shallow needles inserted, 30 min/d×5 treatment sessions for acute stage, 30 min/d×10 treatment sessions, rested for 2-3 days, 2 cycles for resting stage and restoration stage; vs. Drug group: prednisone 5 mg three times/d	Total effective rate The cured rate
Yang et al. 2006 China	320	The facial paralysis diagnostic criteria	Clinical diagnosis: Symptoms, Signs	Horizontal and shallow needles inserted	Combined group: horizontal and shallow needles inserted, 30 min/d×10 treatment sessions, rested for 2 days, total 4 cycles, and drugs; vs. Drugs group: Steroids, Antiviral drugs, Vasodilators and neurotrophic drugs	Total effective rate and the cured rate
Fu et al. 2007 China	52	Traditional Chinese medicine criteria and Western medicine criteria	Efficacy of Traditional Chinese Medicine	Light stimulation methodElectroacupuncture	Acupuncture group: acupuncture during the acute stage, drugs, acupuncture, microwave therapy electroacupuncture the acute stage vs. Drugs group: the same methods as the treatment group but acupuncture was not given at the acute stage	Total effective rate The cured rate

Wang et al. 2007 China	60	The Latest Medical Diagnostic Criteria at Home and Abroad	Symptoms and Signs House-Brackmann scale	Manual acupuncture	Acupuncture and medicine group: needles inserted with manual stimulation till elicited de qi; 30 min/d×6 treatment sessions/week, rested for a day, total 2 cycles, and drugs; vs. Medicine Drugs group: dexamethasone 10 mg/d×4 d, Vitcmin B12 0.5 mg/d + Vitamin B1 100 mg×4 days (im)	Total effective rate
Hou et al. 2008 China	97	Practical Medicine	Clinical diagnosis: Symptom, Sign	Light stimulation method	Combined group: acupuncture at main points in combination with He-Ne laser radiation; VS. Medicine group: intravenous dripping of low molecular dextran, compound Danshen and ATP injections, VitBl and VitBl2, and oral administration of oryzanol and prednisone	Total effective rate The cured rate
Dai et al. 2009 China	72	Traditional Chinese medicine criteria and Western medicine criteria	Clinical diagnosis: Symptom, Sign	Shallow needles inserted Electroacu-puncture	Combined group: shallow needles inserted, electroacupuncture 20-30 min/other day×10 sessions for a cycle; vs. Medicine group: prednison 1 mg/Kg/d×7 d, Vitamin B12 0.5 mg/d, Vitamin B1 100 mg×4-5 weeks (im)	Total effective rate
Tong et al. 2009 China	119	The facial paralysis diagnostic criteria of ENT surgeons	House-Brackmann scale; The degree and speed of recovery	Manual acupuncture	Acupuncture group: needles inserted with manual stimulation till elicited de qi; vs. Medicine group: predni- solone 30 mg twice daily×1 week + pepcidine 20 mg twice daily×1 week	Total effective rate
Xie et al. 2010 China	120	Standard of clinical common diseases diag-nosis and treatment	House-Brackmann scale	Shallow needles inserted	Combined group: shallow needling combined with acupoint ap-plication + the routine medication; vs. Medicine group: routine medication	Total effective rate The cured rate
Liu et al. 2010 China	131	The diagnostic criteria of Traditional Chinese Medicineand Western Medicine	House-Brackmann scale	Horizontal and shal-low needles inserted	Acupuncture group: horizontal and shallow needles inserted, 30 min/d×5 treatment sessions, rested for 2 days, total 4 cycles; vs. Medicine group: prednisone and Acyclovir (po) Vitamin B1 and Vitamin Bl2 (im) in acute stage, acupuncture during quiescent and recovery stages	Total effective rate The cured rate
Zhang et al. 2013 China	60	The diagnostic criteria of Traditional Chinese Medicineand Western Medicine	House-Brackmann scale	Shallow needles in-serted and subexcite	Continued group: drugs, acupuncture and microwave therapy during the acute stage, EA, acupoint injection, electrotherapy and massage during the convalescence stage; vs. Medicine group: 'Shuxuening', dehydrohydrocortisone, vit B1, vit B12, bendazol	Total effective rate The cured rate
Jin et al. 2015 China	156	Traditional Chinese medicine criteria and Western medicine criteria	Symptoms + Signs House-Brackmann scale	Manual acupuncture	Continued group: needle stimulation till elicited de qi; 30 min/d×5 treatment sessions/week, restedfor a day, total 4 cycles; vs. Medi-cine group: steroid, Vitamin B1 and Vitamin Bl2	Total effective rate The cured rate

Abbreviations: EMG, electromyography; ENT, ear-nose-throat department; IM, intramuscular; PO, per os; EA, electro-acupuncture; FDI, facial deformity index.

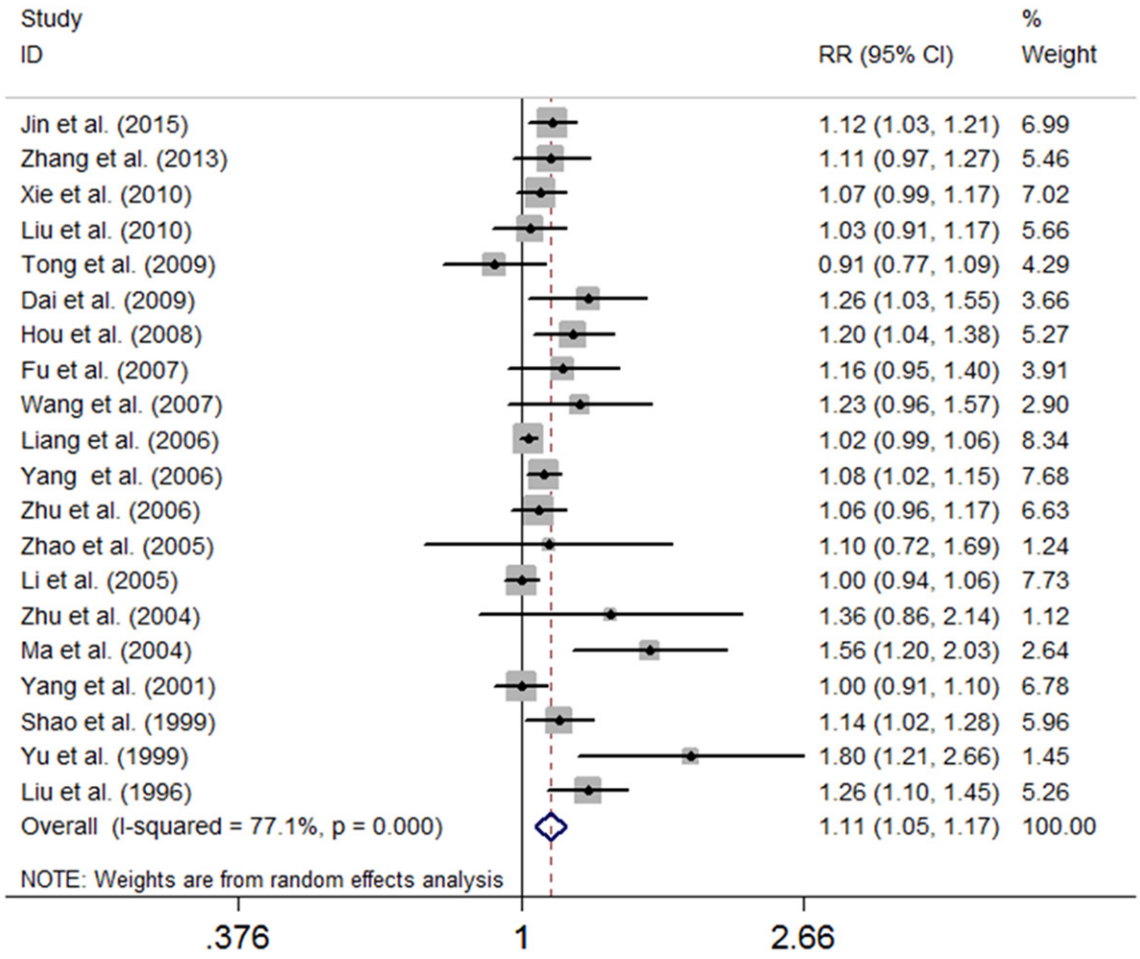

Figure 2. Meta-analysis on acupuncture for total effective rate of Bell's palsy, with the area reflecting the weight assigned to the study. The horizontal line across each square represents the 95% confidence interval. The diamond represents the summary relative risk of total effective rate on acupuncture, with width representing 95% confidence interval.

ly relevant articles from PubMed (48), EMBASE (41) and the Cochrane Central Register of Controlled Trials (155) . Of these, only 21 articles were retained for further review through removing 81 duplications and 142 articles of which themes were not relevant. After browsing the full text for more details, three articles were excluded: one study with mixed interventions both of acupuncture group and the control group [26]; two studies compared different types of the efficacy of acupuncture [27, 28]. Therefore, of the 21 full-text publications obtained, only 18 [29-46] RCTs met our inclusion criteria. By referring to previous meta-analysis and related reviews, the another 2 [47, 48] RCTs were included. Finally, a total of 20 studies were included in our meta-analysis. The characteristics of the 20 included RCTs were summarized in **Table 1**, where they were stratified by chronological order. All these included studies were conducted in China and published from 1996 to 2015. Eighteen studies were written in Chinese and two in English [30, 34]. A total of 2511 participants were enrolled in this meta-analysis with sample sizes ranging from 42 to 480. The patients were randomly assigned to acupuncture group (Intervention group) or control group, with their age ranging from 6 to 72. The average time of appearing facial nerve paralysis relevant clinical symptoms ranges from 1 day to 6 months. Eleven studies compared acupuncture against other interventions: nine RCTs used drug therapy as a control; one RCT used Chinese traditional manipulation [41]; one RCT used stellate ganglion block therapy as a control [47]. In addi-

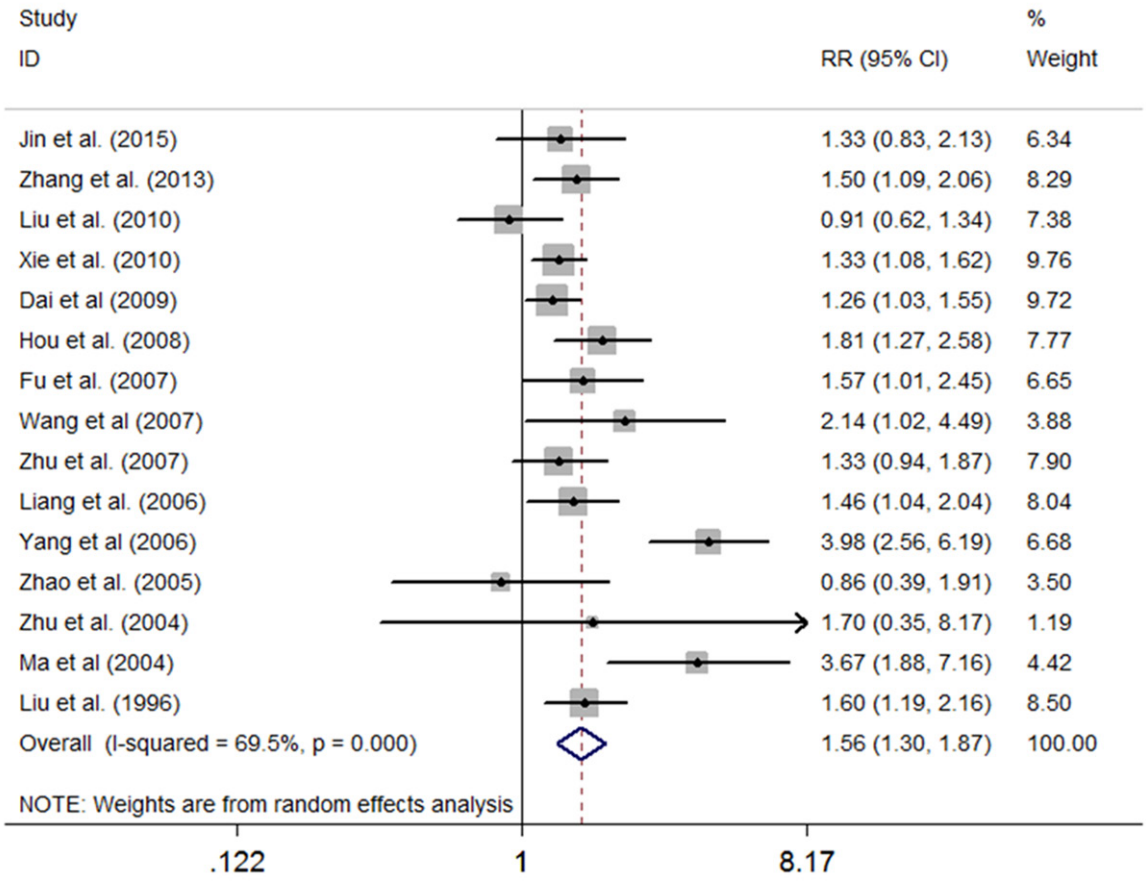

Figure 3. Meta-analysis on acupuncture for cured rate on Bell's palsy, with the area reflecting the weight assigned to the study. The horizontal line across each square represents the 95% confidence interval. The diamond represents the summary relative risk of cured rate on acupuncture, with width representing 95% confidence interval.

tion, nine studies [29-31, 33, 35, 36, 39, 40, 48] compared acupuncture plus other interventions against drug therapy: seven RCTs used acupuncture plus drug therapy against drug therapy; one RCT used acupuncture plus He-Ne laser radiation against drug therapy [35]; one RCT used acupuncture plus moxibustion against drug therapy [40]. Of these included RCTs, seven studies [30, 33, 37, 41, 43, 47, 48] used electro-acupuncture techniques while thirteen studies chose conventional acupuncture techniques. House-Brackmann scoring was used in seven studies [29-32, 34, 36, 40], the Facial paralysis scale was used in two studies [38, 48], symptoms and/or signs was used in five studies [29, 33, 35, 36, 39], while Yanagihara grading scores and local skin temperature change only was used in Liang 2006 as efficacy assessment. The Mean therapy time of the include studies ranged from 10 day to 8 weeks. All studies used total effective rate as an outcome measure. Meanwhile, fifteen studies used the cured rate [29-33, 35-40, 42, 46-48] and one study used the course of cured patient [31] as an outcome measure. Only one RCT referred to adverse effects and/or complications during acupuncture [47]. The others didn't mention about side effects and/or complications. Potential risk of bias was found by reviews' judgment's about each risk of bias item for each included study (Supplementary Figure 1).

Primary outcome: total effective response rate and total cured rate

All the selected 20 studies were used to calculate the pooled estimate for assessing the total effective rate. In total, there were 973 cured individuals among 1004 patients in the acupuncture group (96.90%) and 817 individuals among 945 patients in the control group

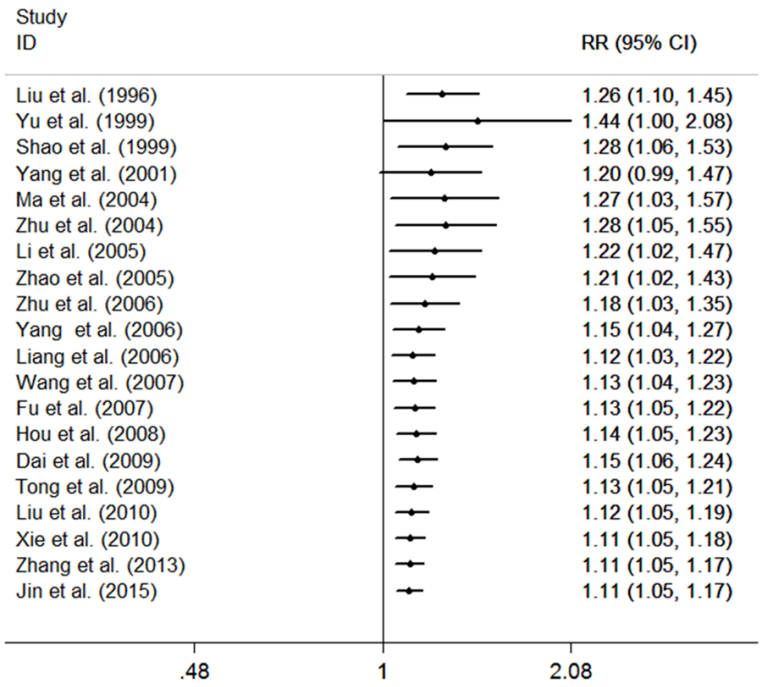

Figure 4. Cumulative meta-analysis on acupuncture for total effective rate of Bell's palsy.

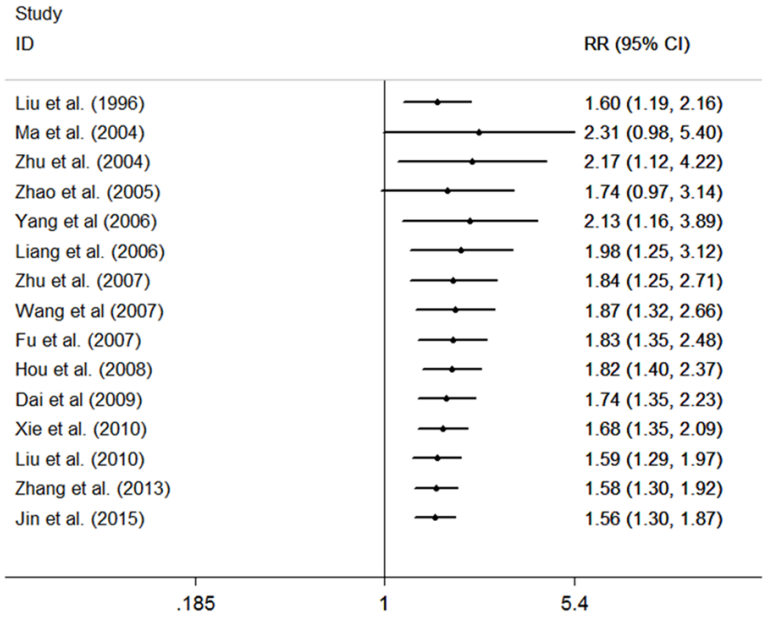

Figure 5. Cumulative meta-analysis on acupuncture for cured rate of Bell's palsy.

(86.46%). The criteria were determined with reference to the House-Brackmann judging and grading system of facial nerve function. We defined total cure rate and total effective rate as our end-points. A random-effect model was applied to pool the results (**Figure 2**): acupuncture therapy was associated with an increased total effective response rate (RR=1.11, 95% CI: 1.05-1.17), with significant heterogeneity (I^2=77.1%, $P_{Heterogeneity}$<0.001). A cumulative meta-analysis was conducted to evaluate the total effective rate in chronological order (**Figure 3**). The results indicated that: 1) The point estimation value of RR and confidence interval tend to be stable and have a preferable variation tendency over time. 2) On the premise of the selected test level, the time of reaching statistical significance began with Ma et al. [42] (RR=1.27, 95% CI: 1.03-1.57).

A total of 15 RCTs were used to calculate the pooled estimate for assessing the cured rate. A random-effect model was used to estimate the results (**Figure 4**): Overall, the total cured rates in the acupuncture and control groups were 61.64% and 38.28%, respectively. Acupuncture therapy was associated with an increased total cured rate (RR=1.56, 95% CI: 1.30-1.87, P<0.000), with significant heterogeneity among the included studies (I^2=69.5%, $P_{Heterogeneity}$<0.001). **Figure 5** showed the results of the cumulative meta-analysis for the total cured rate between the acupuncture group and the control group, which is similar to the total effective rate: 1) Significantly stability can be observed on the point estimation value of RR and its confidence interval over time. 2) On the premise of the selected test level, the time of reaching statistical significance began with Yang et al. [39] (RR=2.13, 95% CI: 1.16-3.89).

Table 2. Subgroup analyses

	N^1	HR (95% CI)	I^2 (%)	$P_{heterogeneity}$	$P_{interaction}$	N^1	HR (95% CI)	I^2 (%)	$P_{heterogeneity}$	$P_{interaction}$
Age										
>40	5	1.18 (1.01, 1.38)	66.2	0.02	0.47	3	1.86 (1.36, 2.55)	0	0.92	0.47
≤40	10	1.11 (1.05, 1.17)	48.4	0.04		8	1.50 (1.20, 1.88)	75.6	0	
Sample size[2]										
>100	10	1.10 (1.04, 1.17)	73	0	0.74	8	1.63 (1.24, 2.16)	79.6	0	0.69
<100	10	1.13 (1.04, 1.23)	58.8	0.01		7	1.43 (1.24, 1.66)	3	0.40	
Therapy period										
>1 month	6	1.18 (1.07, 1.31)	46.8	0.09	0.17	5	1.98 (1.01, 3.88)	86.6	0	0.18
<1 month	14	1.08 (1.03, 1.12)	58.4	0		10	1.42 (1.27, 1.59)	6.2	0.38	
Disease stage										
>3 days	4	1.13 (1.04, 1.21)	6.6	0.36	0.35	4	1.50 (1.23, 1.83)	10.6	0.34	0.29
<3 days	6	1.07 (1.00, 1.15)	26.2	0.24		5	1.29 (1.10, 1.50)	16.2	0.31	
Comparison										
Acu vs. Drug[3]	10	1.10 (1.01, 1.19)	69.5	0	0.82	6	1.44 (1.05, 1.97)	67.2	0.01	0.61
Acu + drug[3] vs. Drug[3]	8	1.11 (1.07, 1.15)	0	0.73		7	1.66 (1.25, 2.20)	74.9	0	
Acu + other[4] vs. Drug[3]	2	1.09 (0.94, 1.27)	78.8	0.03		2	1.61 (1.27, 2.06)	0	0.39	
Acupuncture type										
Electro-acu	6	1.06 (0.98, 1.14)	36.9	0.16	0.43	4	1.29 (1.07, 1.54)	0	0.59	0.55
Manual-acu	5	1.09 (1.00, 1.18)	69.9	0		5	1.66 (1.22, 2.26)	52.6	0.08	
Shallow needle	6	1.09 (1.02, 1.16)	44.5	0.13		4	1.61 (1.00, 2.59)	88.6	0	
Acu with Deqi[5]										
Yes	10	1.09 (1.03, 1.15)	65.6	0.002	0.51	8	1.50 (1.18, 1.90)	52.8	0.04	0.82
No	10	1.14 (1.06, 1.23)	66.6	0.001		7	1.60 (1.24, 2.08)	76.8	0	

Abbreviations: Acu, acupuncture; N, number of studies; CI, confidence interval; RR, relative risk. [1]Number of studies in subgroups. [2]Number of Bell's palsy patients in intervention and controlled group. [3]Steroids, Vitamin B1, Vitamin B12, acyclovir, Chinese traditional medicine and so on. [4]Moxibustion or He-Ne laser radiation. [5]Pins and needles sensation after acupuncture.

Secondary outcomes

Only one RCT referred to adverse effects and/or complications during acupuncture [47]. The others didn't mention about side effects and/or complications. Thus, an evaluation of the incidence of complications was not available, owing to insufficient data.

Subgroup analyses and sensitivity analyses

Several subgroup analyses were conducted to assess the stability of the meta-analysis's results (**Table 2**). Except for electro-acupuncture and acupuncture with moxibustion or He-Ne laser radiation versus medicines subgroups, significant associations between acupuncture and total effective rate or cured rate for Bell's palsy remained in the rest subgroups (**Table 2**). Pooled hazard ratios from the random-effects model and fixed-effects model were virtually identical. Omitting a single study in turn did not significantly change the summary risk estimate of either effective rate or cured rate (Supplementary Figures 2 and 3). Repeating meta-analyses according to various inclusion or exclusion criteria did not change our results, either (Supplementary Table 1).

Substantial publication bias was found in acupuncture-Bell's palsy association (*P* for Begg test=0.03; *P* for Egger test=0.001) for total effective rate, while no evidence of publication bias was found in cured rate (all *P*>0.1).

Discussion

This meta-analysis included 20 RCTs with 2508 Bell's palsy patients and reported the efficacy of acupuncture on Bell's palsy through comparing total effective rate and cured rate with traditional drug treatment. Our study revealed a more convincing positive association between acupuncture and treatment of Bell's palsy, because we contained new researched literature published after 2009 which previous studies did not, and we conducted a cumulative meta-analysis trial according to chronological order. In cumulative analysis, we observed that the RR value of treatment efficacy of acupuncture for Bell's palsy tended to be more stable and CIs became more narrowed. Especially,

this change performed significantly after 2006 of which sample size was high to 908, 36% of total sample size from 1996 to 2015. In despite of these, substantial heterogeneity also existed in this current meta-analysis, and subgroup analyses as well as sensitivity analyses were conducted to explore the potential modifiers.

Jingluo, namely, a system of internal main and collateral channels, regarded as a network of energy passages, along with acupuncture points distributed [49]. Some new research on theory of main and collateral channels with many clinical experiences have fully proved that main and collateral channels is not entirely unreal [50]. It is a functional collection of the nervous system, circulatory system, lymph system, endocrine system, muscle tissue and so on [51, 52]. The acupuncture points, in essence, is a series of micro-vascular with synchronous diastole and contraction [53, 54]. The mechanism of acupuncture treatment could be explained in terms of neurology [55] and microcirculation theories [53, 54] such as activation of receptors, transmission of signals along afferent nerve fibers, projecting into central nervous systems, efferent control mechanisms, improving microcirculation, elimination of inflammation, absorption of edema, strengthening the body resistance and so on. It has been hypothesized that part of the effects of acupuncture may be attributed to diminishment of the muscle tone induced by various motor reflexes [28]. This is especially true for muscles under continuous tonic contraction. The inhibition of the muscle tone by acupuncture stimulation may be related to the functional recovery of the facial nerve and associated muscles. However, these theories are not currently fully established.

Most cases (approximately 70%) of Bell's palsy can recover within 6 months spontaneously. Conventional medical options for Bell's palsy are limited which include care of eyes, corticosteroid or antiviral medications, physical therapy, surgery, and acupuncture. Eye ointment is widely used to avoid trauma and corneal drying. Corticosteroids have been used in facial nerve paralysis, due to powerful anti-inflammatory effect, and have been proven to be an effective treatment. Regarding to facial nerve injury, electrical response grading is superior to the House-Brackmann scale in efficacy and reliability, and can conveniently assess the degree of facial nerve injury. The House-Brackmann scale is suitable for the patients with mild facial nerve injury, but its evaluated quality for severe facial nerve injury is poor [56]. According to a recent study, the effect of steroids on acute Bell's palsy within 72 h of the onset of symptoms is clinically effective, but steroids have not been used on Bell's palsy for long time [57]. Previous studies have shown that some patients of bell's palsy in presence of herpes simplex virus infection [16, 26, 56, 58, 59]. Namely, antiviral agents can be applied in some cases. As optional treatments of Bell's palsy, no particular benefits of physical therapy or surgical operation have been reported [19, 59, 60]. Acupuncture is known as a safe treatment used for a wide range of symptoms over all stages associated with Bell's palsy [61]. Acupuncture for the disease, by contrast, has advantage for efficacy, safety, simple, little side effects and wide clinical applications.

Significant heterogeneity was found in included studies. After conducting subgroup analyses and sensibility analyses stratified by age, the heterogeneity decreased to 0% on the subgroup of age more than 40. In respect to contrast design, of the studies with acupuncture plus drug versus only drug treatment, heterogeneity in total effective rate decreased by about 43% while not showed in cured rate, whose comparison is more reasonable [62]. As for sample size and therapy period, we only observed significant decline of heterogeneity in total effective rate or cured rate since limited sample size, methodology defects and mixed treatment restrict our analyses. In addition, heterogeneity in studies stratified by disease stage shrinks both in total effective rate and cured rate, which plausibly owed to this self-limited characteristic. Besides, sensitivity analyses indicated that heterogeneity in the studies evaluating efficacy by facial paralysis score or House-Brackmann scoring lower by at least 63% which were also suggested by recent guideline [63]. In conclusion, acupuncture type, disease stage and evaluated criterion of efficacy of acupuncture possibly are potential modifiers.

Strength and limitation

Clearly the major strength of this meta-analysis is that we have analyzed what we believe to be all available data from comprehensive litera-

ture retrieval of acupuncture for Bell's palsy. Data capture is perhaps the most important aspect of comprehensive meta-analysis with such large combinations of data across an extensive number of studies. Additionally, our analysis showed a modest effect for acupuncture compared with control group, cumulative meta-analyses were first to be conducted. Superior efficacy for Bell's palsy being suggested in previous meta-analyses [15] can't explain the high heterogeneity between studies, further analyses were carried out, such as subgroup analyses and sensitivity analyses. To shrink this heterogeneity, attentions were proposed for later studies.

We acknowledge several limitations of our analysis. Firstly, poor methodological quality of eligible studies raised concerns of reliability for our results, what's more, increasing bias risk. Then, definitions of efficacy in different studies varied, and we cannot exclude misclassification. In addition, many variables had influenced on outcomes, such as course or duration of treatment, characteristic of subjects and disease stages. We were unable to perform dose-response meta-analysis due to insufficient data and Bell's palsy is a self-limited disease affecting observation of efficacy. Lastly, publication bias existed in our meta-analysis.

Conclusion

In summary, different comparisons, acupuncture regimens and disease stages showed opposite results on efficacy of Bell's palsy. Therefore, RCTs should not combine these when examining acupuncture's efficacy. Meanwhile, we can't draw a conclusion since these findings should be interpreted with caution due to limited methodological quality studies and potential biases, and need to be validated by more well designed and large sample size RCTs.

Acknowledgements

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Disclosure of conflict of interest

None.

Abbreviations

RCT, randomized controlled trial; RR, relative risk; CI, confidence interval.

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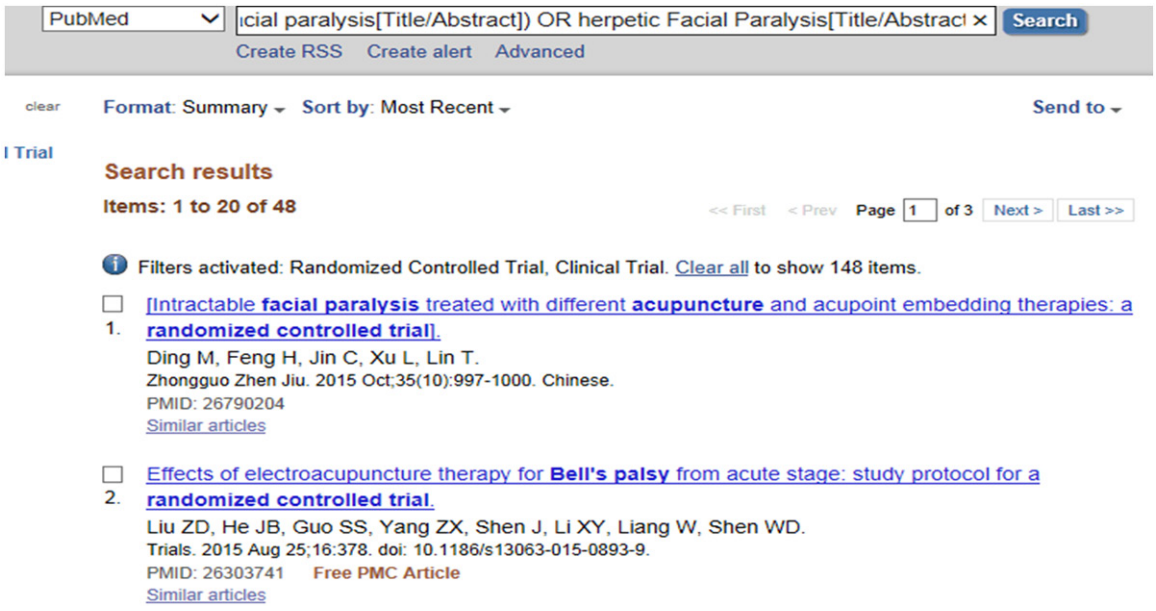
Supplementary List 1-Search Strategy

Pubmed (n=48)

#1: "Search acupuncture [Title/Abstract]"
#2: "Search acupuncture therapy [Title/Abstract]"
#3: "Search (acupuncture [Title/Abstract]) OR acupuncture therapy [Title/Abstract]"
#4: "Search Bell's palsy [Title/Abstract]"
#5: "Search facial paralysis [Title/Abstract]"
#6: "Search idiopathic facial paralysis [Title/Abstract]"
#7: "Search herpetic Facial Paralysis [Title/Abstract]"
#8: "Search (((Bell's palsy [Title/Abstract]) OR facial paralysis [Title/Abstract]) OR idiopathic facial paralysis [Title/Abstract]) OR herpetic Facial Paralysis [Title/Abstract]"
#9: "Search ((acupuncture [Title/Abstract]) OR acupuncture therapy [Title/Abstract]) AND ((((Bell's palsy [Title/Abstract]) OR facial paralysis [Title/Abstract]) OR idiopathic facial paralysis [Title/Abstract]) OR herpetic Facial Paralysis [Title/Abstract])"
#10: "Search ((acupuncture [Title/Abstract]) OR acupuncture therapy [Title/Abstract]) AND ((((Bell's palsy [Title/Abstract]) OR facial paralysis [Title/Abstract]) OR idiopathic facial paralysis [Title/Abstract]) OR herpetic Facial Paralysis [Title/Abstract]) Filters: Randomized Controlled Trial"
#11: "Search ((acupuncture [Title/Abstract]) OR acupuncture therapy [Title/Abstract]) AND ((((Bell's palsy [Title/Abstract]) OR facial paralysis [Title/Abstract]) OR idiopathic facial paralysis [Title/Abstract]) OR herpetic Facial Paralysis [Title/Abstract]) Filters: Randomized Controlled Trial; Clinical Trial".



History

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Search	Add to builder	Query	Items found	Time
#11	Add	Search **(((acupuncture[Title/Abstract]) OR acupuncture therapy[Title/Abstract])) AND ((((Bell's palsy [Title/Abstract]) OR facial paralysis[Title/Abstract]) OR idiopathic facial paralysis[Title/Abstract]) OR herpetic Facial Paralysis[Title/Abstract])** Filters: **Randomized Controlled Trial; Clinical Trial**	48	11:34:58
#10	Add	Search **(((acupuncture[Title/Abstract]) OR acupuncture therapy[Title/Abstract])) AND ((((Bell's palsy [Title/Abstract]) OR facial paralysis[Title/Abstract]) OR idiopathic facial paralysis[Title/Abstract]) OR herpetic Facial Paralysis[Title/Abstract])** Filters: **Randomized Controlled Trial**	42	11:34:52
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#6	Add	Search **idiopathic facial paralysis[Title/Abstract]**	152	11:32:05
#5	Add	Search **facial paralysis[Title/Abstract]**	4775	11:31:51
#4	Add	Search **Bell's palsy[Title/Abstract]**	1995	11:31:29
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#2	Add	Search **acupuncture therapy[Title/Abstract]**	738	11:30:50
#1	Add	Search **acupuncture[Title/Abstract]**	17241	11:30:29

EMBASE (n=41)

#1. 'acupuncture': ab, ti
#2. 'acupuncture therapy': ab, ti
#3 #1 OR#2
#4. 'bell palsy': ab, ti
#5. 'facial paralysis': ab, ti
#6. 'idiopathic facial paralysis': ab, ti
#7. 'herpetic facial paralysis': ab, ti
#8. #4 OR#5 OR#6 OR#7
#9. #3 AND #8
#10. #9 AND ([controlled clinical trial]/lim OR [randomized controlled trial]/lim).

#10	#3 AND #8 AND ([controlled clinical trial]/lim OR [randomized controlled trial]/lim)	41
#9	#3 AND #8	145
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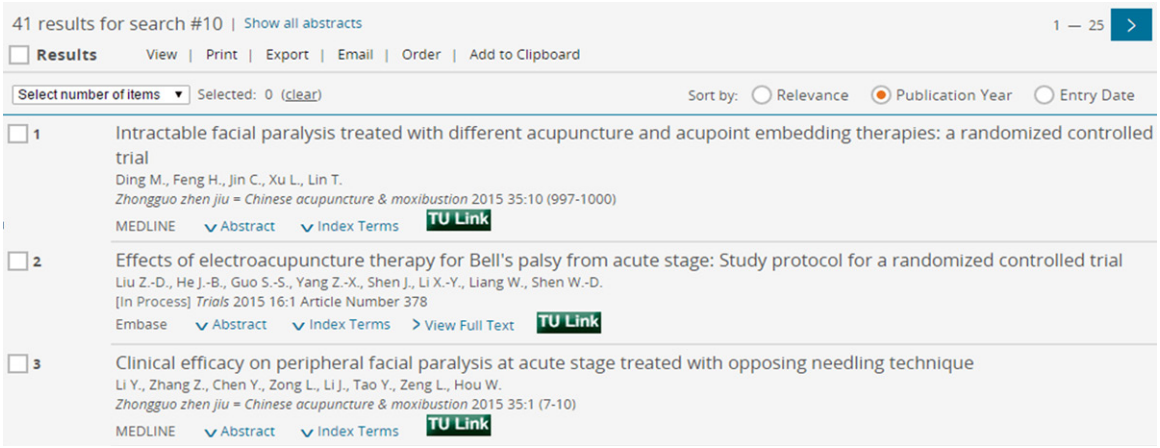
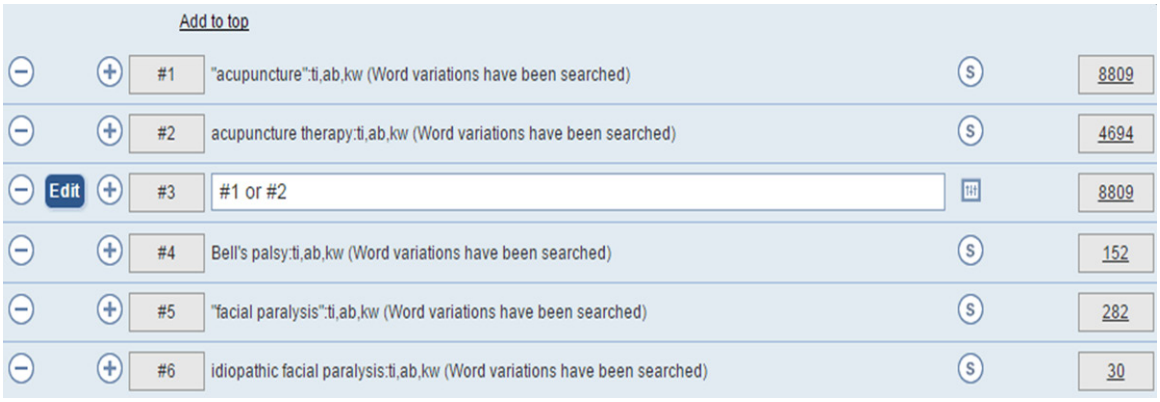
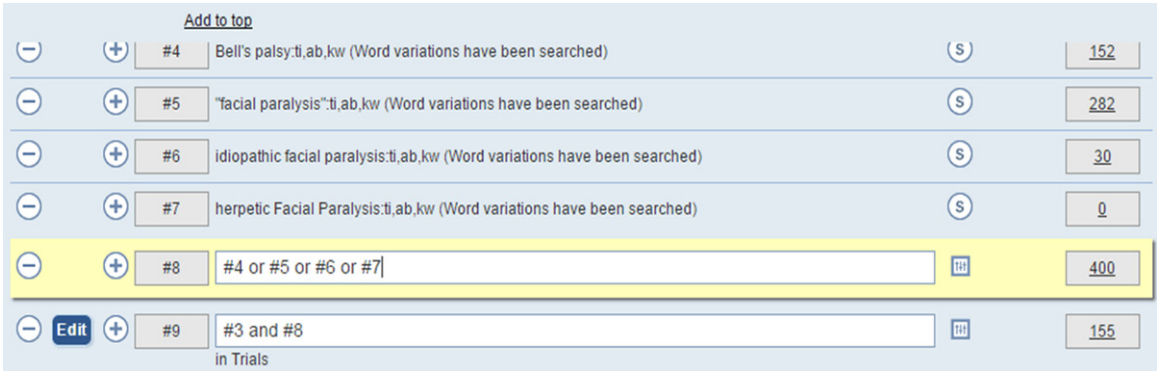


Cochrane library (n=155)

#1 "acupuncture": ti, ab, kw
#2 acupuncture therapy: ti, ab, kw
#3 #1 or #2
#4 Bell's palsy: ti, ab, kw
#5 "facial paralysis": ti, ab, kw
#6 idiopathic facial paralysis: ti, ab, kw
#7 herpetic Facial Paralysis: ti, ab, kw
#8 #4 or #5 or #6 or #7
#9 #3 and #8 in Trials.






Cochrane Central Register of Controlled Trials : Issue 6 of 12, June 2016

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Pages 1 - 25 | 26 - 50 | 51 - 75 | 76 - 100 | 101 - 125 | Next Sort by Relevance: high to low

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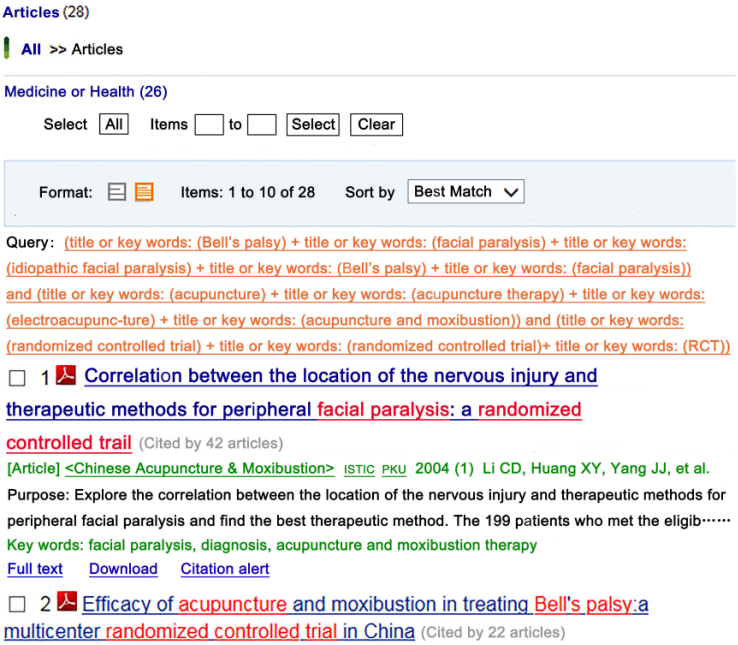
Sanqi tongshu capsule for acute idiopathic facial paralysis: A clinical controlled trial. [Chinese]
Liu J , Wu J-F and Wei Y-S
Chinese Journal of Evidence-Based Medicine, 2010, 10(1), 30
Publication Year: 2010

A prospective randomised controlled study on efficacies of acupuncture and steroid in treatment of idiopathic peripheral facial paralysis.
Tong FM , Chow SK , Chan PY , Wong AK , Wan SS , Ng RK , Chan G , Chan WS , Ng A and Law CK
Acupuncture in medicine : journal of the British Medical Acupuncture Society, 2009, 27(4), 169
Publication Year: 2009

WanFang (n=38)

(title or key words: (Bell's palsy) + title or key words: (facial paralysis) + title or key words: (idiopathic facial paralysis) + title or key words: (Bell's palsy) + title or key words: (facial paralysis)) and (title or key words: (acupuncture) + title or key words: (acupuncture therapy) + title or key words: (electroacupuncture) + title or key words: (acupuncture and moxibustion)) and (title or key words: (randomized controlled trial) + title or key words: (randomized controlled trial) + title or key words: (RCT)).


Articles (28)

All >> Articles

Medicine or Health (26)

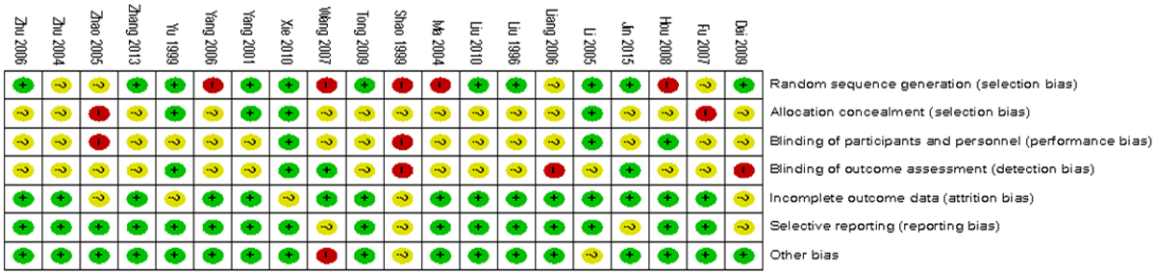
Select All Items to Select Clear

Format: Items: 1 to 10 of 28 Sort by Best Match

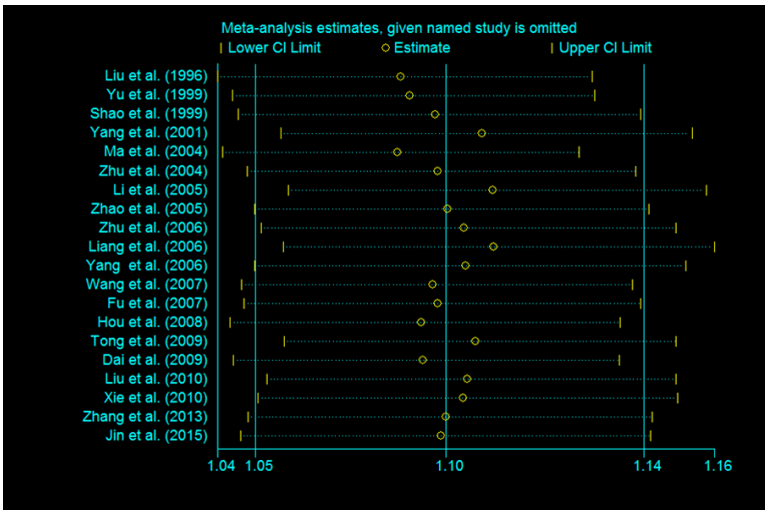
Query: (title or key words: (Bell's palsy) + title or key words: (facial paralysis) + title or key words: (idiopathic facial paralysis) + title or key words: (Bell's palsy) + title or key words: (facial paralysis)) and (title or key words: (acupuncture) + title or key words: (acupuncture therapy) + title or key words: (electroacupunc-ture) + title or key words: (acupuncture and moxibustion)) and (title or key words: (randomized controlled trial) + title or key words: (randomized controlled trial)+ title or key words: (RCT))

1 Correlation between the location of the nervous injury and therapeutic methods for peripheral facial paralysis: a randomized controlled trail (Cited by 42 articles)
[Article] <Chinese Acupuncture & Moxibustion> ISTIC PKU 2004 (1) Li CD, Huang XY, Yang JJ, et al.
Purpose: Explore the correlation between the location of the nervous injury and therapeutic methods for peripheral facial paralysis and find the best therapeutic method. The 199 patients who met the eligib……
Key words: facial paralysis, diagnosis, acupuncture and moxibustion therapy
Full text Download Citation alert

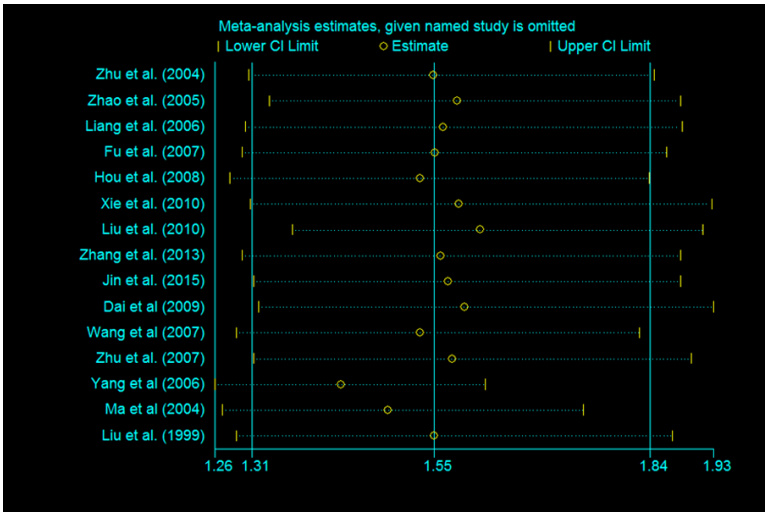
2 Efficacy of acupuncture and moxibustion in treating Bell's palsy:a multicenter randomized controlled trial in China (Cited by 22 articles)



Supplementary Figure 1. Risk of bias summary: review authors' judgments about each risk of bias item for each included study.



Supplementary Figure 2. Sensitivity analysis on acupuncture for total effective rate of Bell's palsy.



Supplementary Figure 3. Sensitivity analysis on acupuncture for cured rate of Bell's palsy.

Supplementary Table 1. Sensitivity analysis

	Total effective rate			Total cured rate		
	N	HR (95% CI)	I^2 (%)	N	HR (95% CI)	I^2 (%)
Random effect model	20	1.11 (1.05, 1.17)	77.1	15	1.56 (1.30, 1.87)	69.5
Fixed effect model	20	1.12 (1.09, 1.15)	77.1	15	1.62 (1.47, 1.80)	69.5
Within						
Using facial paralysis or House-Brackmann scoring	10	1.05 (1.02, 1.09)	13.7	9	1.32 (1.17, 1.50)	0
Reported both effective rate and cured rate	15	1.11 (1.07, 1.16)	54.1	15	1.55 (1.31, 1.84)	65.7
Without						
Sample size <100	10	1.09 (1.03, 1.16)	76.7	8	1.64 (1.22, 2.22)	81.5
Extra therapy method[1]	17	1.10 (1.05, 1.15)	58.1	15	1.55 (1.31, 1.84)	65.7
Therapy period >1 month	14	1.08 (1.03, 1.14)	74.5	10	1.42 (1.27, 1.59)	6.9

Abbreviations: N, number of studies; CI, confidence interval; RR, relative risk. [1]moxibustion or He-Ne laser radiation.